IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VIIV HEALTHCARE COMPANY, SHIONOGI & CO., LTD., and VIIV HEALTHCARE UK (NO. 3) LIMITED, Plaintiffs, v. LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC., Defendants.	)	Case No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs ViiV Healthcare Company, Shionogi & Co., Ltd., and ViiV Healthcare UK (No. 3) Limited (collectively, "Plaintiffs" or "ViiV") bring this action for patent infringement against Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, "Defendants" or "Lupin").

THE PARTIES

1. Plaintiff ViiV Healthcare Company, a wholly owned subsidiary of ViiV Healthcare Limited, is a corporation organized and existing under the laws of the State of Delaware, with a trading address at Five Moore Drive, Research Triangle Park, North Carolina 27709.

2. Plaintiff Shionogi & Co., Ltd., also known as Shionogi Seiyaku Kabushiki Kaisha, is a corporation organized and existing under the laws of Japan, with a principal place of business at 1-8, Doshomachi 3-chome, Chuo Ku, Osaka, 541-0045, Japan.

3. Plaintiff ViiV Healthcare UK (No. 3) Limited is a corporation organized and existing under the laws of the United Kingdom, with a registered office at 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom.

4. On information and belief, Defendant Lupin Limited is a corporation organized and existing under the laws of the India, with a registered office at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India.

5. On information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202.

6. On information and belief, Defendants are in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including within this District.

7. On information and belief, Lupin Pharmaceuticals, Inc. is a wholly owned subsidiary of Lupin Limited.

8. On information and belief, Defendants acted in concert to develop the proposed generic product that is the subject of Abbreviated New Drug Application ("ANDA") No. 213120 and to seek regulatory approval from the U.S. Food and Drug Administration ("FDA") to market and sell such proposed generic product throughout the United States, including within this District.

9. On information and belief, Lupin Pharmaceuticals, Inc. USA acts as the U.S. agent of Lupin Limited with respect to ANDA No. 213120 and Lupin Pharmaceuticals, Inc. will

work, either directly or indirectly, to manufacture, import, market, and sell the proposed generic product.

10. On information and belief, ANDA No. 213120 references a Drug Master File for dolutegravir sodium held by Lupin Limited.

NATURE OF THE ACTION

11. This is a civil action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of Defendants' ANDA No. 213120, filed with the FDA. Defendants' ANDA No. 213120 seeks approval to engage in the commercial manufacture, use and sale of Dolutegravir Sodium and Rilpivirine Hydrochloride Tablets, 50 mg/25 mg ("Proposed ANDA Product"), which is a generic version of Plaintiffs' JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25 mg, prior to the expiration of Plaintiffs' U.S. Patent Nos. 9,242,986 ("the '986 Patent") and 10,426,780 ("the '780 Patent").

JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action, which arises under the patent laws of the United States, pursuant to 28 U.S.C. §§ 1331 and 1338(a), and 35 U.S.C. § 1 *et seq*.

13. This Court has personal jurisdiction over Defendants because, *inter alia*, they have maintained continuous and systematic contacts with the State of Delaware and this District.

14. On information and belief, Defendants collaborate to market and sell generic pharmaceutical products, pursuant to the Abbreviated New Drug Application process, throughout the United States, including in the State of Delaware, at least by making and shipping into this judicial district, or by offering to sell or selling, or causing others to offer to sell or sell, generic

pharmaceutical products. Defendants derive substantial revenue from goods used or consumed or services rendered in this judicial district.

15. This Court has personal jurisdiction over Lupin Limited by virtue of, *inter alia*, its conduct of business in this District, its purposeful availment of the rights and benefits of Delaware law, and its substantial, continuous, and systematic contacts with the State of Delaware. On information and belief, Lupin Limited: (1) intentionally markets and provides its generic pharmaceutical products to residents of this State; (2) enjoys substantial income from this State; (3) created a presence in the State through its related company, Lupin Pharmaceuticals, Inc.; and (4) affirmatively avails itself of the jurisdiction of this Court by filing counterclaims in this District and by being sued in this District without challenging personal jurisdiction. *See, e.g.*, *Bayer Intellectual Property GMBH et al. v. Lupin Limited et al.*, 1:17-cv-01047 (D. Del.); *Omeros Corp. v. Lupin Ltd. et al.*, 1:17-cv-00803 (D. Del.); *ViiV Healthcare Company et al. v. Lupin Limited et al.*, 1:17-cv-00315 (D. Del.); *Arena Pharmaceuticals, Inc. et al. v. Lupin Ltd. et al.*, 16-cv-00887 (D. Del.); *ViiV Healthcare Company et al. v. Lupin Limited et al.*, 1:17-cv-01576 (D. Del.).

16. This Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. by virtue of, *inter alia*, its conduct of business in this District, its purposeful availment of the rights and benefits of Delaware law, and its substantial, continuous, and systematic contacts with the State of Delaware. On information and belief, Lupin Pharmaceuticals, Inc.: (1) is incorporated in the State of Delaware; (2) intentionally markets and provides its generic pharmaceutical products to residents of this State; (3) enjoys substantial income from this State; and (4) affirmatively avails itself of the jurisdiction of this Court by filing counterclaims in this District and by being sued in this District without challenging personal jurisdiction. *See, e.g., Bayer Intellectual Property*

GMBH et al. v. Lupin Limited et al., 1:17-cv-01047 (D. Del.); *Omeros Corp. v. Lupin Ltd. et al.*, 1:17-cv-00803 (D. Del.); *ViiV Healthcare Company et al. v. Lupin Limited et al.*, 1:17-cv-00315 (D. Del.); *Arena Pharmaceuticals, Inc. et al. v. Lupin Ltd. et al.*, 16-cv-00887 (D. Del.); *ViiV Healthcare Company et al. v. Lupin Limited et al.*, 1:17-cv-01576 (D. Del.).

17. On information and belief, Lupin Limited directly or through its subsidiaries, including Lupin Pharmaceuticals, Inc., manufactures, imports, markets, and sells generic drugs throughout the United States and in this judicial district.

18. On information and belief, Defendants intend to manufacture for distribution, and to distribute and sell, products that are generic equivalents of Plaintiffs' JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25 mg, throughout the United States and in this District.

19. For the reasons set forth above, for the reasons set forth in the Court of Appeals for the Federal Circuit's decision in *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755 (Fed. Cir. 2016), and for additional reasons which will be supplied if Defendants challenge personal jurisdiction in this action, Defendants are subject to personal jurisdiction in this District.

20. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b), (c) and 1400(b).

THE PATENTS-IN-SUIT

21. The '986 Patent, entitled "Synthesis of carbamoylpyridone HIV integrase inhibitors and intermediates," was duly and legally issued on January 26, 2016 and will expire on December 8, 2029. A copy of the '986 Patent is attached as Exhibit A. Shionogi & Co., Ltd. is the assignee of the '986 Patent. ViiV Healthcare UK (No. 3) Limited is the exclusive licensee of the '986 Patent.

22. The ’780 Patent, entitled “Antiviral therapy,” was duly and legally issued on October 1, 2019 and will expire on January 24, 2031. A copy of the ’780 Patent is attached as Exhibit B. ViiV Healthcare Co. is the assignee of the ’780 Patent. ViiV Healthcare UK (No. 3) Limited is the exclusive licensee of the ’780 Patent.

FACTUAL BACKGROUND

JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25 mg

23. JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25 mg, are approved by the FDA as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25 mg.

24. ViiV Healthcare Company is the holder of approved New Drug Application No. 210192 for JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25 mg.

25. JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25 mg, are covered by one or more Claims of the ’986 and ’780 Patents, and the ’986 and ’780 Patents have been listed for NDA No. 210192 in the FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the “Orange Book.”

26. ViiV sells and distributes JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25 mg, in the United States pursuant to NDA No. 210192.

Defendants' ANDA No. 213120

27. By the Notice Letter dated January 16, 2020, Defendants notified Plaintiffs that Defendants, by submitting ANDA No. 213120 to the FDA seek approval to engage in the commercial manufacture, use and sale of the Proposed ANDA Product prior to the expiration of the '986 and '780 Patents, and that ANDA No. 213120 included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the '986 and '780 Patents are allegedly invalid, unenforceable and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Proposed ANDA Product.

28. On information and belief, Defendants were necessarily aware of the Patents-in-Suit when ANDA No. 213120 was filed with the Paragraph IV Certification.

29. On information and belief, dolutegravir sodium as covered in one or more of the Claims of the '986 and '780 Patents are and/or will be present in the Proposed ANDA Product.

30. On information and belief, ANDA No. 213120 refers to and relies upon NDA No. 210192 for JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25 mg, and contains data that, according to Defendants, demonstrate the bioequivalence of the Proposed ANDA Product and JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25 mg.

31. On information and belief, the Proposed ANDA Product will have instructions for use that substantially copy the instructions for JULUCA® (Dolutegravir Sodium/Rilpivirine Hydrochloride) Tablets, 50 mg/25 mg. The instructions accompanying the Proposed ANDA Product will induce others to use and/or contribute to others' use of the Proposed ANDA Product in the manner set forth in the instructions.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 9,242,986

32. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1-31 of this Complaint.

33. The Proposed ANDA Product infringes one or more Claims of the '986 Patent, either literally or under the doctrine of equivalents.

34. Defendants' submission of ANDA No. 213120 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the '986 Patent constitutes infringement of one or more Claims of the '986 Patent under 35 U.S.C. § 271(e)(2).

35. On information and belief, Defendants plan to, intend to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 213120 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

36. On information and belief, upon FDA approval of ANDA No. 213120, Defendants will infringe the '986 Patent under 35 U.S.C. § 271(a), literally and/or through the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States.

37. Upon FDA approval of ANDA No. 213120, Defendants will infringe the '986 Patent under 35 U.S.C. § 271(a), literally and/or through the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and will infringe under 35 U.S.C. § 271(b) and/or (c), literally and/or through the doctrine of equivalents, by actively inducing and/or contributing to infringement by others.

38. Defendants' January 16, 2020 Notice Letter does not dispute that the Proposed ANDA Product will infringe Claims 1-6 of the '986 Patent unless Claims 1-6 of the '986 Patent are found invalid.

39. On information and belief, Defendants had knowledge of the '986 Patent when they submitted ANDA No. 213120 to the FDA, and Defendants know or should know that they will aid and abet another's direct infringement of at least one of the Claims of the '986 Patent.

40. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

41. On information and belief, Defendants lacked a good faith basis for alleging non-infringement of Claims 7-12 and invalidity of Claims 1-12 of the '986 Patent when they filed their Paragraph IV Certification. Accordingly, Defendants' Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 10,426,780

42. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1-41 of this Complaint.

43. The Proposed ANDA Product infringes one or more Claims of the '780 Patent, either literally or under the doctrine of equivalents.

44. Defendants' submission of ANDA No. 213120 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the '780 Patent constitutes infringement of one or more Claims of the '780 Patent under 35 U.S.C. § 271(e)(2).

45. On information and belief, Defendants plan to, intend to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 213120 and will direct physicians and patients on the use of the Proposed ANDA Product through product labeling.

46. On information and belief, upon FDA approval of ANDA No. 213120, Defendants will infringe the '780 Patent under 35 U.S.C. § 271(a), literally and/or through the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States.

47. Upon FDA approval of ANDA No. 213120, Defendants will infringe the '780 Patent under 35 U.S.C. § 271(a), literally and/or through the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and will infringe under 35 U.S.C. § 271(b) and/or (c), literally and/or through the doctrine of equivalents, by actively inducing and/or contributing to infringement by others.

48. Defendants' January 16, 2020 Notice Letter does not dispute that the Proposed ANDA Product will infringe Claims 1-17 of the '780 Patent unless Claims 1-17 of the '780 Patent are found invalid.

49. On information and belief, Defendants had knowledge of the '780 Patent when they submitted ANDA No. 213120 to the FDA, and Defendants know or should know that they will aid and abet another's direct infringement of at least one of the Claims of the '780 Patent.

50. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

51. On information and belief, Defendants lacked a good faith basis for alleging non-infringement of Claims 1-17 and invalidity of Claims 1-17 of the ’780 Patent when they filed their Paragraph IV Certification. Accordingly, Defendants’ Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court grant the following relief:

a) Judgment that the ’986 and ’780 Patents are valid and enforceable;

b) Judgment that Defendants’ submission of ANDA No. 213120 was an act of infringement under 35 U.S.C. § 271(e)(2) of one or more Claims of the ’986 and ’780 Patents;

c) Judgment that Defendants’ making, using, offering to sell, selling, or importing into the United States of the Proposed ANDA Product prior to the expiration of the ’986 and ’780 Patents, will infringe, will actively induce infringement, and/or will contribute to the infringement of one or more Claims of the ’986 and ’780 Patents;

d) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 213120 shall be a date that is not earlier than the expiration of the ’986 and ’780 Patents plus any other exclusivity to which Plaintiffs are or become entitled;

e) An Order permanently enjoining Defendants, their affiliates and subsidiaries, each of their officers, agents, servants and employees, and any person acting in concert with Defendants, from making, using, offering to sell, selling, marketing, distributing, or importing into the United States the Proposed

ANDA Product until after the expiration of the '986 and '780 Patents plus any other exclusivity to which Plaintiffs are or become entitled;

f) A declaration that this case is an exceptional case within the meaning of 35 U.S.C. § 285, and an award to Plaintiffs' of their reasonable costs and attorneys' fees incurred in connection with this action; and

g) Such further and other relief as this Court deems proper and just.

Dated: February 28, 2020

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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